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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,956	01/29/2001	Michele Bennett Kinrade	U 013223-9	9691

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EXAMINER

WEGERT, SANDRA L

ART UNIT PAPER NUMBER

1647

DATE MAILED: 03/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n No.

09/771,956

Applicant(s)

KINRADE ET AL.

Examiner

Sandra Wegert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 December 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-90 is/are pending in the application.
- 4a) Of the above claim(s) 10-90 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-90 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 6.                      6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Application, Amendments, and/or Claims***

The Information Disclosure Statement, received 23 October 2002 (Paper 5), and the Information Disclosure Statement, received 8 November 2002 (Paper 6), have been entered into the record. Applicant's election of Invention I (claims 1-9) in Paper No. 8 is acknowledged. In addition, Applicant elected: SEQ ID NO: 9.

Applicant traversed the first Restriction and argued that the claims of Inventions I-IV should be rejoined, since they are all related to the chimeric NPY receptor of Group I, and therefore a search of the art for Group I should reveal the relevant art for the other three Inventions. However, the claims of Inventions I-IV were restricted properly, because the products of Inventions I and II are independent and distinct, have different putative functions, have different structures, and require completely different search terms, starting points and strategies, and because the methods of Invention II-IV are independent and distinct in that they are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps, and goals. The methods of transfecting cells with DNA to produce a protein are different from methods of assaying ligands for a receptor. As well, a method of treating a disease in a multicellular organism requires completely different starting materials (e.g., animals as opposed to membranes or tissues), goals, measurements and personnel.

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Claims 10-90 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Inventions, there being no allowable generic or linking claims.

Claims 1-9 are under examination in the Instant Application.

### **Informalities**

#### ***Specification***

The disclosure is objected to because of the following informalities:

#### ***URL's***

The disclosure is objected to because it contains browser-executable code. This occurs, for example, on p. 2, line 7. All URL's should be removed from the Specification. Applicant may refer to web sites by non-executable name only. See MPEP § 608.01 (p).

Appropriate correction is required.

### **Claim Objections/Rejections**

#### ***Claim Rejections - 35 USC § 112, first paragraph – Written Description.***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

**The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in**

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the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-9 are directed to a chimeric NPY receptor constructed of 15 segments from NPY5 receptors and NPY1 receptors. The segments are divided approximately by location in the membrane and alternating hydrophobicity (for example: extracellular domain (hydrophilic)- transmembrane domain (hydrophobic)- intracellular domain (hydrophilic), - transmembrane domain (hydrophobic), etc).

The specification as originally filed does not provide adequate written description for a chimeric protein of the general formula: *NPY5 receptor N-terminal extracellular domain- first transmembrane domain – first intracellular loop domain, - second transmembrane domain, etc.* The exact limitations of the chimeric receptor are not expressly asserted nor do they flow naturally from the specification as originally presented.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116).

The specification as originally filed does not provide adequate written description of the subgenus now claimed. The specification teaches a chimeric NPY receptor of SEQ ID NO: 9. Agonist binding experiments and G-protein transduction events were measured with the polypeptide of SEQ ID NO: 9. However, the specification does not provide adequate support for a peptide of the formula: *NPY5 receptor N-terminal extracellular domain- first transmembrane domain – first intracellular loop domain, - second transmembrane domain, etc.*

Therefore, only a peptide of the formula: *NPY5 receptor N-terminal extracellular domain- first transmembrane domain – first intracellular loop domain, - second transmembrane domain, etc.*, with a clearly-defined amino acid sequence (e.g., SEQ ID NO: 9), but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

### ***35 U.S.C. 112, First paragraph- Enablement***

Claims 1-9 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-9 are directed to an NPY receptor protein, comprised of 15 separate segments of the formula: *NPY5 receptor N-terminal extracellular domain- first transmembrane domain – first intracellular loop domain, - second transmembrane domain, etc.*

The specification teaches the polypeptide of SEQ ID NO: 9. However, the specification does not teach functional or structural characteristics of the chimeric NPY receptor polypeptide recited in the claims. Furthermore, it is not obvious from a general description of a chimeric receptor what the precise functional characteristics of the receptor might be.

In addition, describing the polypeptide as a chimeric NPY receptor, based on structural components of the receptor, is not sufficient to ascribe a function to the receptor. For example, Skolnick et al. (2000, Trends in Biotech. 18:34-39) state that knowing the protein structure by itself is insufficient to annotate a number of functional classes, and is also insufficient for annotating the specific details of protein function (see Box 2, p. 36). Likewise, Smith et al. (1997, Nature Biotechnology 15:1222-1223) remark that there are numerous cases in which proteins share structural similarity due to evolution from a common ancestral gene yet have unpredictable functions. Brenner (1999, Trends in Genetics 15:132-133) argues that accurate inference of function from homology must be a difficult problem since, assuming there are only about 1000 major gene superfamilies in nature, then most homologues must have different molecular and cellular functions.

Furthermore, incorporating orthologous domains from the NPY receptors of other species of organisms, as recited in Claims 3, 6 and 9, does not guarantee a specific function or a conservation of function across species. This was demonstrated by Gerlt, J. and Babbitt, P. (2000, Genome Biology, 1: 1-10) who showed that two enzymes from different species, characterized as orthologs based on structure, catalyzed very different reactions (see p. 6).

Therefore, based on the discussions above concerning the specific examples of structurally similar proteins that have different functions, along with the art's recognition that one cannot rely upon a structural description alone to determine functionality, the specification fails to teach the skilled artisan how to use the description of a chimeric NPY receptor to make a biologically active polypeptide or to determine the specific biological activities of the claimed polypeptides.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Due to the large quantity of experimentation necessary to --determine an activity or property of the disclosed polypeptide such that it can be determined how to use the claimed chimeric receptor and to screen for activity, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art establishing that biological activity cannot be predicted based on a structural description and the unpredictability of the effects of mutation on protein structure and function, as well as the breadth of the claims which fail to recite particular biological activities -- undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.



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Conclusion:

Claims 1-9 are rejected for the reasons cited above.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:30 AM to 6:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623. Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Elyabek C. Hemmen*

SLW

3/18/03

ELIZABETH C. HEMMEN  
PATENT ATTORNEY